

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Blood Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

DMB

Display Date	8/23/01
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Certifier	<i>R. DeLeon</i>

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Blood Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 20, 2001, from 8 a.m. to 5 p.m., and on September 21, 2001, from 8 a.m. to 3:30 p.m.

Location: Hilton DC North—Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD.

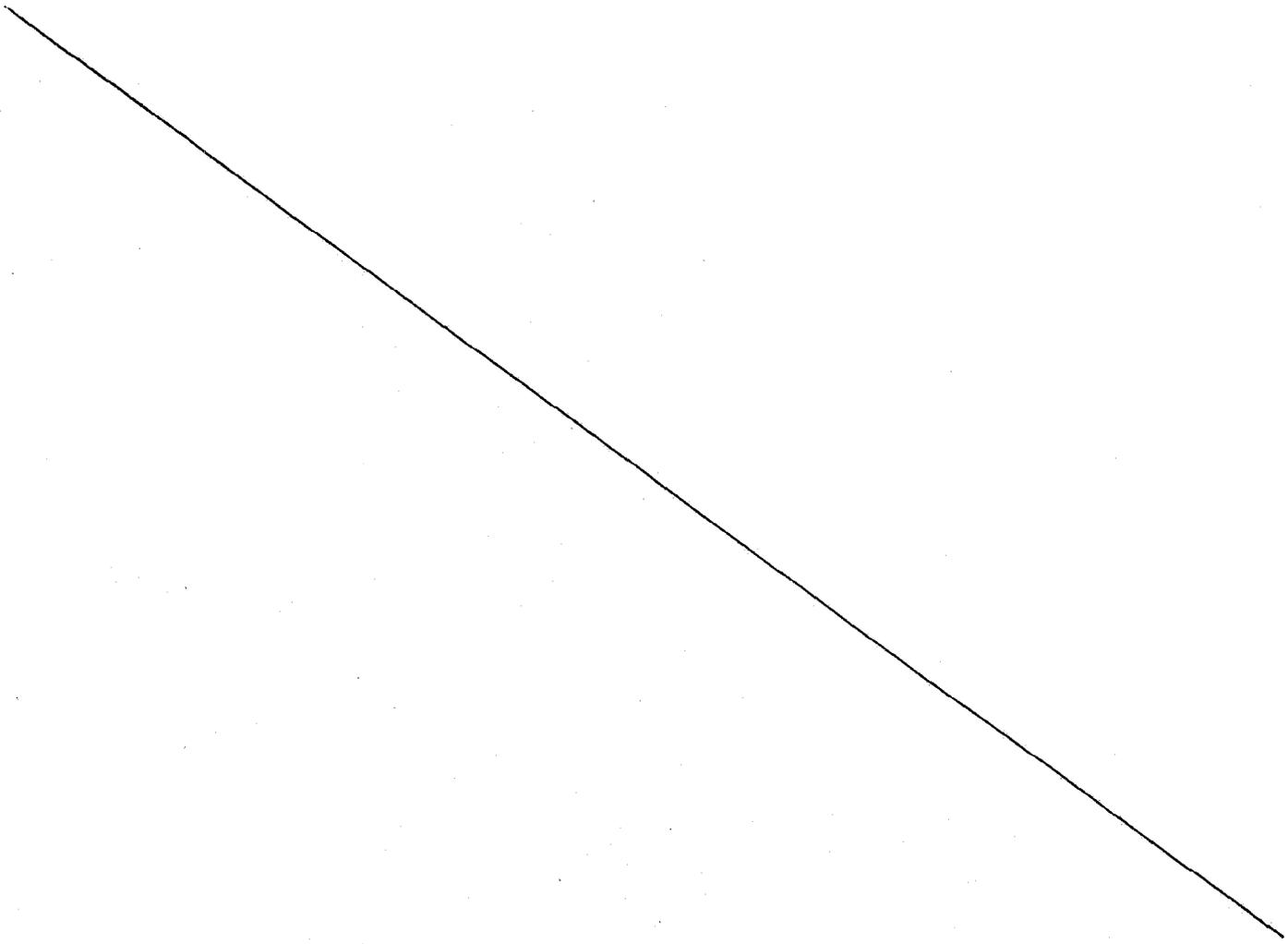
Contact: Linda A. Smallwood, Center for Biologics Evaluation and Research (HFM-302), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-3514, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 19516. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 20, 2001, the following committee updates are tentatively scheduled:

- (1) Transmissible spongiform encephalopathies guidance; hepatitis B surface antigen lot release guidance; human immunodeficiency virus (HIV) and hepatitis C virus nucleic acid testing; Clinical Laboratory Improvement Act waiver for HIV rapid tests; and
- (2) compliance quality control oversight. In the morning, the committee will hear presentations, discuss and make recommendations on potential concerns for simian foamy virus transmission by blood and blood products. In the afternoon, the committee will hear presentations, discuss and make

recommendations on the leukocyte reduction guidance. On September 21, 2001, the committee will hear presentations, discuss and make recommendations on human cells, tissues and cellular and tissue-based products: risk factors for semen donation.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 2001. Oral presentations from the public will be scheduled between approximately 12 noon and 12:30 p.m., and 3:45 p.m. and 4:45 p.m. on September 20, 2001; and between approximately 11:30 a.m. and 1 p.m. on September 21, 2001. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 8/16/01
August 16, 2001.


Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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